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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,834	05/26/2005	Peter C. Harris	07039-386US1	6384
26191 7590 01/27/2009 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER BERTAGNA, ANGELA MARIE				
ART UNIT		PAPER NUMBER		
1637				
NOTIFICATION DATE		DELIVERY MODE		
01/27/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/501,834

Applicant(s)

HARRIS ET AL.

Examiner

ANGELA BERTAGNA

Art Unit

1637

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-13,16-19,29-37,40,43-60 and 103-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,5,8-13,16-19,29-37,40,43-60 and 103-108.

DETAILED ACTION

Status of the Application

1. Applicant's response filed on October 14, 2008 electing species (iv), deletion of the adenine at position 9689 of SEQ ID NO: 1, is acknowledged. Upon further consideration, it has been determined that the restriction requirement mailed on September 18, 2008 inadvertently failed to address the fact that the claim amendments submitted on June 20, 2008 require further consideration of the original restriction requirement mailed on June 19, 2007. In view of the amendments to the claims submitted on June 20, 2008, the isolated nucleic acid products presented in claims 1, 2, 5, 8-13, 16-19, 29-37, 40, 43-51, 60, and 104 overlap in scope with the primer pairs of claims 52-59 and 105-108. Accordingly, a new restriction requirement addressing this issue is presented below. The Examiner regrets any inconvenience resulting from the issuance of this new restriction requirement.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 2, 5, 8-13, 16-19, 29-37, 40, 43-60, and 104-108, drawn to compositions comprising isolated nucleic acids and primer pairs.

Group II, claim(s) 103, drawn to a method for diagnosing autosomal recessive polycystic kidney disease.

3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The prior art of Park et al. (Genomics 57:249-255, 1999; cited on the IDS) teaches all of the limitations of the instant claim 1. Park teaches a 1-Mb BAC/PAC-based physical map that refines the localization of PKHD1, flanked by the markers D6S1714/D6S243 and D6S1024 (see abstract, Figure 1, and pages 249-250). Thus, Park teaches an isolated nucleic acid that encodes a fibrocystin polypeptide. Since the prior art of Park teaches all of the limitations of the instant claim 1, the claims lack a special technical feature linking them over the prior art, and therefore, restriction is proper.

Sequence Restriction

4. This application also contains claims drawn to a plurality of isolated nucleic acids and variants thereof (see claims 1, 2, 5, 8-13, 16-19, 29-37, 40, 43-60, 104, and 105-108). As noted in MPEP 803.04:

By statute, '[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.' 35 U.S.C. 121. Pursuant to this statute, the rules provide that '[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted.' 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Polynucleotide molecules defined by their nucleic acid sequence (hereinafter 'nucleotide sequences') that encode different proteins are structurally distinct chemical compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*

In this case, the claims are drawn to a plurality of isolated nucleic acids and variants thereof (claims 1, 2, 5, 8-13, 16-19, 29-37, 40, 43-51, 60, and 104). The claims are also drawn to primer pairs for amplifying the isolated nucleic acids and variants thereof (see claims 52-59 and 105-108). Each of the recited nucleic acids is a structurally distinct molecule and can be used in separate and distinct methods. Since each of the isolated nucleic acids recited in the claims are independent and distinct inventions by statute, Applicant is required to elect the following for examination:

(i) a single isolated nucleic acid from SEQ ID NO: 1, 3, and 4 and identify the corresponding amino acid sequence (*i.e.* SEQ ID NO: 2, 6, or 7);

(ii) If SEQ ID NO: 1 and SEQ ID NO: 2 are elected in (i), Applicant is further required to elect a single variant from those recited in claims 9-12, 16-19, 29-36, 43-45, 50, 51, and 105-108 for examination. In making this election, Applicant should indicate where the elected amino acid position is located in the corresponding polynucleotide sequence or *vice versa*.

Applicant is also reminded to clearly identify those claims that read on the elected species.

The above election is not an election of species. As noted in the Official Gazette Notice published on March 27, 2007 titled "Examination of Patent Applications Containing Nucleotide Sequences", the partial waiver of the requirements for restriction pursuant to 37 CFR 1.141 *et*

seq, permitting examination of a reasonable number, normally up to ten, independent and distinct nucleic acids in a single patent application, has been rescinded. This Official Gazette Notice states that “[P]olynucleotide inventions will be considered for restriction, rejoinder and examination practice in accordance with the standards set forth in MPEP Chapter 800 (except for MPEP 803.04 which is superceded by this Notice). Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule.”

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/

Examiner, Art Unit 1637

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